

In re Patent Application

Brockhaus et al.

Serial No.: 08/444,791

Filed: May 19, 1995

For: HUMAN TNF RECEPTOR

Commissioner of Patents
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

_____ page(s) of substitute Sequence Listing.

_____ computer disk(s) containing substitute Sequence Listing.

_____ Statement under 37 CFR §1.825(b) that the computer disk and paper copies of the substitute Sequence Listing are the same.

_____ Statement under 37 CFR §1.825(a) that the substituted Sheets of the Sequence Listing are supported in the application.

_____ No additional fee is required.

_____ Petition for an extension of time under 37 CFR §1.136.

Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110
August 24, 2000

Examiner: T. Cunningham

Art Unit: 1644

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DEPOSIT ACCOUNT

NO. 08-2525

OUR ORDER NO. 3344

Serial No. 08/444,791
Filed: May 19, 1995

(Col. 1)		(Col. 2)		(Col. 3)		
CLAIMS REMAINING AFTER AMENDMENT			HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDIT. FEE
TOTAL	34	MINUS	18	16	x \$18	\$288.00
INDEP.	4	MINUS	10	0	x \$78	\$0
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+ 260	
TOTAL						\$288.00

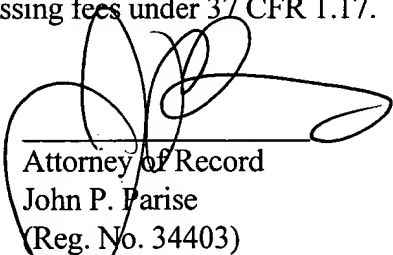
X Please charge my Deposit Account No. 08-2525 in the amount of \$ \$288.00. This sheet is provided in triplicate.

 A check in the amount of \$ is attached.

X The Commissioner is hereby authorized to charge payment of the following fees or any additional fees associated with this communication or credit any overpayment to Deposit Account No. 08-2525. This sheet is provided in triplicate.

X Any filing fees under 37 CFR 1.16 for the presentation of extra claims.

X Any patent application processing fees under 37 CFR 1.17.



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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Brockhaus *et al.*

Serial No.: 08/444,791

Filed: May 19, 1995

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Examiner: T. Cunningham

Art Unit: 1644

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AUG 31 2000

TECH CENTER 1600/2800

For: HUMAN TNF RECEPTOR

WITHDRAWAL OF MOOTED
REQUEST FOR INTERFERENCE

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This paper is submitted with reference to, and for the purpose of withdrawing, our previously filed request for interference with Beutler *et al.*, U.S. Patent No. 5,447,851 ("the '851 patent"). As detailed below, that request for an interference has been rendered moot by the PTO's subsequent reexamination of the '851 patent and the resulting narrowing of the '851 claims. In view of this action, it is submitted that the proper course of action in this application is to resume *ex parte* examination, enter the accompanying amendment and pass the application to allowance.

August 24, 2000

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BACKGROUND

Our request for interference, filed in 1996, presented an independent claim that was copied from the '851 patent. The PTO did not declare an interference, but instead granted a request by the patentee for *reexamination* of the '851 patent. Reexamination was ordered, in part, in view of the disclosure contained in this application. The PTO rejected and ultimately *cancelled* the broad patent claim that had been copied, as being unpatentable over the disclosure contained in this application. All of the '851 claims which survived reexamination were limited by restrictive amendment to distinguish over the disclosure contained in this application.

In view of this, the PTO acknowledged that the captioned application is prior art to the '851 patent, and that the applicants herein were the first to invent the subject matter cancelled from the '851 patent. Therefore, there is no longer any need for an interference with the '851 patent to settle this matter.

Indeed, by issuing a reexamination certificate which confirmed that the significantly narrowed '851 claims are patentable over the disclosure of this application, the PTO has effectively made an administrative determination that there is no "interference-in-fact" between the surviving '851 claims and applicants' claims, including the claim that was copied from the '851 patent. An interference is thus no longer needed. In fact, an interference would not be permissible under the applicable rules, as we detail below.

1. The Applicable Rules

An interference may be declared between a patent of one party and an application of another party only if there exists an "interference-in-fact." An interference-in-fact exists only when "at least one claim of a party . . . and at least one claim of an opponent . . . define the *same patentable invention.*" 37 CFR § 1.601(j).

As recently explained by the Board in *Winter v. Fujita*, 53 USPQ2d 1234, 1243 (BPAI 1999), claims define the “same patentable invention,” and therefore create an interference-in-fact, only if a claim of one party renders unpatentable a claim of another party and vice-versa. The Board emphasized that an interference-in-fact must be shown to exist by application of the following two-way test:

Resolution of an interference-in-fact issue involves a two-way patentability analysis. The claimed invention of Party A is presumed to be prior art vis-à-vis Party B and vice versa. The claimed invention of Party A must anticipate or render obvious the claimed invention of Party B and the claimed invention of Party B must anticipate or render obvious the claimed invention of Party A.

When an applicant seeking to provoke an interference copies a patent claim there is necessarily an interference-in-fact, because the applicant’s claim renders unpatentable the patentee’s identical claim -- and vice-versa. When the claims in issue are not identical, however, they may or may not define the same patentable invention. For example, if the subject matter of a patentee’s species claim is non-obvious in view of an applicant’s generic claim, the claims do not define the same patentable invention and there is no interference-in-fact. This is so even though the species claim would anticipate the generic claim. *Cf. Hester v. Allgeier*, 209 USPQ 370, 378 (CCPA 1981).

When claims do not define the same patentable invention, and an interference-in-fact does not exist, each party is entitled to a patent containing its respective claims. *See Hsing v. Myers*, 2 USPQ2d 1861, 1866 (BPAI 1987).

2. The Copied '851 Patent Claim And Request For Interference

In our request for interference with the '851 patent, we presented the following copied claim, which substantially corresponded to claim 1 of the '851 patent, the broadest claim in the '851 patent:

66. A DNA segment having a sequence encoding a chimeric polypeptide comprising the extracellular domain of a TNF receptor polypeptide functionally attached to a Fc portion and hinge region of an IgG heavy chain polypeptide.

The DNA of the copied claim encodes a chimeric polypeptide or fusion protein having (1) a TNF receptor portion and (2) an immunoglobulin (Ig) portion. Those portions are encoded, respectively, by two different DNA sequences.

The request for interference did not present any claims copied from the '851 patent which corresponded to the narrow subject matter of dependent claim 4 of the '851 patent.^{1/} That dependent claim recited that a "cleavable linker" DNA sequence is positioned between the two coding sequences called for by claim 66 above.

Applying the interference-in-fact test discussed above, since the copied claim presented by applicants was identical in all relevant respects^{2/} to claim 1 of the '851 patent, there was necessarily an interference-in-fact. The PTO was thus provided with the opportunity to declare an interference and determine which party was entitled to a patent containing the broad copied claim.

^{1/} A copy of the '851 patent is attached hereto as Tab A.

^{2/} The copied claim (66) omitted the '851 claim recitation that the DNA was "isolated," a recitation incapable of imparting patentable distinction to the extent that neither chimeric DNA exists in nature.

3. The Reexamination And Cancellation Of The Copied '851 Claim

Shortly after our request for interference, the assignee of the '851 patent filed a request for reexamination in view (1) of Smith *et al.*, U.S. Patent No. 5,395,760; (2) Smith *et al.*, European Patent Application No. 0 418 014 A1; and (3) Smith *et al.*, European Patent No. 0 418 014 B1 (the "Smith" documents). The PTO ordered reexamination of the '851 patent, finding that the cited Smith documents raised a substantial new question of patentability. The PTO also ordered reexamination, *sua sponte*, in view of Brockhaus, *et al.*, U.S. Patent No. 5,610,279 ("the '279 patent"). The instant application is a continuation of the '279 patent and thus has disclosure identical to the '279 patent.^{3/}

In the paper ordering reexamination, Examiner Furman pointed to specific description in the '279 patent of each of the limitations recited in the broad (copied) '851 claim, *viz.*, (1) "extracellular domain of a TNF receptor polypeptide" and (2) "Fc portion and hinge region of an IgG heavy chain polypeptide." The Examiner stated, in particular:

[Brockhaus] claims the protein product (see claim 1 of Brockhaus *et al.*) of the same DNA in instant claim 1 of the '851 [Beutler] patent and suggests this same DNA in lines 50-56 of col. 5 of Brockhaus *et al.* Regarding the receptor portion of the chimeric molecules, the limitation to "a soluble fragment of the insoluble TNF receptor" in the disclosure and first claim of Brockhaus *et al.* reads on the "extracellular domain of a TNF receptor polypeptide" of claim 1 of the [Beutler] '851 patent. Similarly, regarding the IgG portion, the region of "all of the domain of the constant region of a human immunoglobulin heavy chain other than the first domain of said constant region" in the disclosure and claims 1-6 of Brockhaus *et al.* is equivalent to the region of the "Fc portion and hinge region of an IgG heavy chain polypeptide" in claim 1 of the [Beutler] '851 patent when the IgG is human IgG.

^{3/} A copy of the '279 patent is attached hereto as Tab B.

In the first Office Action, Examiner Carlson rejected claims 1, 2, 6, 7, 11, 13, 15, 16, and 19 of the '851 patent under § 102(e) as anticipated by the '279 patent. Claims 1, 2, 6, 7, and 11-19 were rejected under § 103(a) as obvious in view of the '279 patent. In making the rejections, the Examiner referred to another portion of the '279 disclosure which anticipated the broad claims of the '851 patent:

In Example 11, Brockhaus *et al.* teach the ligation of cDNA encoding human TNF-BP, which is the extracellular or soluble domain of the TNF receptor, into pCD4-Hy β vector from which the CD4 cDNA had been removed. This plasmid was expressed in J5558 myeloma cells. Therefore, DNA having the sequence encoding a chimeric polypeptide comprising the extracellular domain of the human TNF receptor functionally attached to the Fc and hinge region of IgG heavy chain (Claims 1, 2) and in the form of a plasmid or vector (Claims 6, 7, 11) which is transfected into a recombinant eukaryotic host cell (Claims 15, 16) and secreted therefrom (Claim 19) is taught in the prior art [Brockhaus].

Examiner Carlson further explained that certain dependent claims of the '851 patent had not been rejected, because they recited structural elements not disclosed or suggested by the '279 patent:

Claims 3-5, 8-10, and 20-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The assignee of the '851 patent conceded the unpatentability of its broad claims in view of the '279 patent. All claims of the '851 patent were limited to incorporate the patentably distinguishing limitation recited in unrejected dependent claim 4, *viz.*, a "DNA segment encoding a specifically cleavable linker peptide functionally interposed between the TNF receptor

polypeptide and the Fc portion.” Claim 4 as amended, now Beutler Reexam claim 1,^{4/} is reproduced below:

4. An isolated DNA segment having a sequence encoding a chimeric polypeptide comprising the extracellular domain of a TNF receptor polypeptide functionally attached to a Fc portion and hinge region of an IgG heavy chain polypeptide and further incorporating a DNA segment encoding a specifically cleavable linker peptide functionally interposed between the TNF receptor polypeptide and the Fc portion.

In the ensuing Notice Of Intent To Issue Reexamination Certificate,^{5/} under the heading “Statement of Reasons for Patentability,” the Examiner again noted that the ‘279 patent did not describe or suggest a DNA encoding a TNF-Ig fusion protein wherein the DNA includes an intermediate segment which encodes a specifically cleavable linker:

Patent owner (In Paper #9, filed March 16, 1998) has canceled claims anticipated or rendered obvious over the teachings of Brockhaus et al. (USP 5,610,279). Additionally, patent owner has amended claims 4 and 9 to include the limitations of the independent claims and therefore recite that the functional attachment of the TNF receptor extracellular domain to the IgG heavy chain by a protease specific linker, as suggested by the Examiner. Therefore, these claims are not anticipated or rendered obvious over Brockhaus et al. (USP 5,610,279).

4. Reexamination Of The ‘851 Patent Eliminated An Interference-In-Fact

Applying the interference-in-fact test discussed above, since broad claim 1 of the ‘851 patent was been cancelled during reexamination, it no longer creates an interference-in-fact with respect to applicants’ claims, including the broad claim copied from the ‘851 patent.

In addition, because the narrowed surviving claims of the reexamined ‘851 patent have been found to be (1) not anticipated by and (2) not obvious in view of the *entirety* of the

^{4/} A copy of the ‘851 reexamination certificate is attached hereto as Tab C.

^{5/} A copy of the complete reexamination prosecution history of the ‘851 patent is attached hereto as Tab D.

instant disclosure, they are not directed to the "same patentable invention" and do not create an interference-in-fact with respect to applicants' pending claims. During the *ex parte* reexamination proceedings, the PTO necessarily made relevant factual determinations and legal conclusions which would have been addressed in an *inter partes* interference. In particular, the surviving '851 claims have been found to be patentably distinct from the *entirety* of the instant disclosure and, necessarily, from any pending claim or prospective claim which is or could be supported by the instant application. The PTO has already determined that the captioned application is prior art to the '851 patent, and that applicants herein were the first inventors of the subject matter cancelled from the '851 patent.

Thus, no interference can be declared between the reexamined '851 patent and the instant application. Having determined that the assignee of the '851 patent is entitled to a patent containing its narrowed and patentably distinct claims, it necessarily follows that applicants herein are entitled to a patent containing their broader claims. *Hsing*, 2 USPQ2d at 1866.

In view of the foregoing, applicants hereby withdraw the mooted request for interference. It is requested that *ex parte* examination of the application be resumed, that the accompanying amendment be entered and that all of applicants' claims be allowed.

Respectfully submitted,

By: 

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